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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/03/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/744,085

Applicant(s)

Schaffer et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 7/16/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-28 and 31-32 is/are pending in the application.
- Of the above claim(s) 11-16, 20-22, 24, 26, 28, 31-32 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-10, 17-19, 23, 25, 27 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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The preliminary amendment of 21 June 2002 has been entered-in-part. The amendments to the claims, abstract and sequence listing have been entered. However, the amendments to the specification have not been entered, because there was no marked-up copy of these amendments, as required by revised 37 CFR 1.121(c). Applicants are requested to resubmit these amendments in the proper format.

Applicant's election without traverse of Group I in Paper No. 14 is acknowledged. Claims 1-10, 17-19, 23, 25 and 27 are examined.

The application should be reviewed for errors. See, e.g., page 5 of the specification, lines 5-6, in the recitation of "marker includes step of selecting includes" which is awkward. See the suggested language in the rejection of claim 6 under 35 USC 112, second paragraph below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in its recitation of "ADPGPPase" as it is unclear to what this abbreviation refers. Indicating the full name of the enzyme in its first recitation in the claims would obviate this rejection. Thus, replacement of "ADPGPPase" in claim 3 with --ADP-glucose pyrophosphorylase (ADPGPPase)-- would obviate this rejection.

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Claim 6 is indefinite in its recitation of "said molecular marker comprises step of selecting comprises a...subunit" which is awkward and also unclear in its designation of a molecular marker as being equivalent to an enzymatic subunit. The following amendment would obviate this rejection:

replace "comprises step of selecting comprises" with --is diagnostic for--.

Claims 25 and 27 are indefinite in their recitation of "fruit [or seed] produced by a plant in accordance with claim 23", which is confusing, since claim 23 is drawn to a plant, rather than a method for producing fruit or seed. The following amendments would obviate this rejection:

replace "a" with --the-- and replace "in accordance with" with --of--.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 17-19, 23, 25 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a plant produced by introgressing any green-fruited tomato species with cultivated tomato, wherein said introgression transmits any gene that somehow increases starch synthesis, or wherein said gene encodes for a multitude of enzymes that somehow increase starch synthesis. In contrast, the specification only provides guidance for a

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plant produced by crossing *L. hirsutum* and *L. esculentum*, wherein said cross results in the transfer of an *L. hirsutum* gene encoding the large subunit of ADP-glucose pyrophosphorylase. No guidance is presented for crossing any other green-fruited tomato species with *L. esculentum*, or for the identification or transfer of any other gene.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of making or using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description

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Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 1-10, 17-19, 23, 25 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for crossing *L. hirsutum* and *L. esculentum* to introgress the *L. hirsutum* allele encoding the large subunit of ADP-glucose pyrophosphorylase, and methods for selecting plants with higher activity of this enzyme in young fruit, or PCR selection using a probe corresponding to the *L. hirsutum* allele coding for the large subunit of ADPGPPase; does not reasonably provide enablement for claims broadly drawn to crossing *L. esculentum* with any green-fruited *Lycopersicon* species, any gene somehow increasing starch synthesis, any enzyme involved in starch metabolism, any method of selection for increased starch anywhere in the plant and at any developmental stage, or any method of molecular marker-based selection for any gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a plant produced by introgressing any green-fruited tomato species with cultivated tomato, wherein said introgression transmits any gene that somehow increases starch synthesis anywhere in the tomato plant, or wherein said gene encodes for a multitude of enzymes that somehow increase starch synthesis anywhere in the tomato plant. The claims are also broadly drawn to methods of selecting desired products of this cross, via assaying starch production anywhere in the plant and at any developmental stage, by assaying the

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activity of any enzyme involved in starch metabolism, or by using any type of molecular marker corresponding to any gene (claims 5-6).

In contrast, the specification only provides guidance for a plant produced by crossing *L. hirsutum* and *L. esculentum*, wherein said cross results in the transfer of an *L. hirsutum* gene encoding the large subunit of ADP-glucose pyrophosphorylase, and wherein said gene results in increased starch accumulation in immature tomato fruit which is correlated with increased soluble solids content in mature fruit. Furthermore, the specification only provides guidance for the measurement of starch synthesis or ADPGPPase activity in young fruit, and for the use of PCR to identify the *L. hirsutum* allele encoding the large subunit of ADPGPPase. No guidance is presented for crossing any other green-fruited tomato species with *L. esculentum*, or for the identification or transfer of any other gene. In addition, no guidance is presented for the assaying of other plant parts at other developmental stages for starch production or the activity of a multitude of non-exemplified enzymes. Finally, no guidance is presented for the use of a multitude of non-exemplified molecular marker techniques such as RFLP, SSR, etc corresponding to a multitude of non-exemplified genes.

The transfer of genes from wild tomato species conferring high soluble solids in mature tomato fruit (sometimes correlated with increased starch synthesis in young tomato fruit) is unpredictable. Azanza et al teach that *L. chmielewskii* genes which confer increased starch synthesis in young fruit do not confer increased soluble solids content in mature fruit (see, e.g., page 495, Abstract; page 501, column 2, bottom paragraph; page 502, paragraph bridging the

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columns). Yelle et al (1988) teach that *L. chmielewskii* tomato fruit accumulates less starch than *L. esculentum* tomato fruit (see, e.g., page 737, Abstract; page 738, paragraph bridging the columns). Miron et al teach that *L. hirsutum* fruits generally accumulate less starch than *L. esculentum* (see, e.g., page 623, Abstract). Thus, the ability of even this exemplified green-fruited species to confer higher starch accumulation is unpredictable and unexpected.

The use of starch production assays in non-fruit plant parts such as leaves, stems or roots to predict starch accumulation or soluble solids content in mature fruits is unpredictable and unlikely to succeed, given the contradictory teachings of correlation of starch production with soluble solids even in a single organ, as discussed above. Furthermore, given the teachings in the art (see, e.g., Azanza et al, page 495, column 2, bottom paragraph) and the instant specification that starch disappears from mature tomato fruits, assaying mature tomato fruits would not work.

Assaying the activity of a multitude of non-exemplified enzymes for their ability to identify tomato fruits with higher soluble solids or increased starch accumulation is unpredictable. Schaffer et al (1997, Plant Physiology) teach that only a few enzymes were associated with starch metabolism (see, e.g., page 739, Abstract). Furthermore, the instant specification teaches that only APDGPPase activity was consistently correlated with higher starch production in immature fruit produced by an interspecific cross (see, e.g., page 10, Table 1).

The use of molecular markers to identify genes involved in carbohydrate metabolism in tomato is unpredictable. Van Ooijen et al teach that the use of *L. peruvianum* versus *L. pennellii* as parents with *L. esculentum* resulted in the assignment of different gene orders in chromosomes

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1, 4, 9 and 12, based upon RFLP marker analysis (see, e.g., page 1010, Figure 1). In addition, only the large subunit of the exemplified ADPGPPase gene from *L. hirsutum* was demonstrated to confer increased starch accumulation in immature fruit (see, e.g., page 12 of the specification, lines 6-25; page 13, lines 1-8).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and evaluate a multitude of non-exemplified wild tomato species for their ability to confer starch accumulation in immature fruit and increased soluble solids in mature fruit. Undue experimentation would have also been required to assay for the activity of a multitude of non-exemplified enzymes, to assay a multitude of non-exemplified plant organs or developmental stages, or to develop and evaluate a multitude of non-exemplified molecular marker techniques corresponding to either the exemplified *L. hirsutum* allele encoding the large subunit of ADPGPPase or corresponding to a multitude of non-exemplified genes from a multitude of non-exemplified sources encoding a multitude of non-exemplified enzymes.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 25 and 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hewitt et al in light of Rick.

The claims are broadly drawn to tomato plants derived by crossing *L. esculentum* with a wild tomato species, wherein said plants produce immature fruit with higher starch content and mature fruit with higher soluble solids content. The claims are also drawn to seeds and fruits of the plants.

Hewitt et al teach plants, fruits and seeds of LA 1563, which breeding line produces immature fruit having higher starch content and mature fruit having higher soluble solids content than conventional tomato cultivars (see, e.g., page 896, Abstract; page 899, Figure 4). Hewitt et al teach that LA 1563 was first disclosed by Rick (see page 896, first column, third full paragraph,

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footnote 10). Rick teach that LA 1563 was derived by crossing *L. esculentum* with the green-fruited wild tomato species *L. minutum* (see, e.g., page 493, column 2, bottom paragraph).

The tomato plants, fruits and seeds taught by the prior art differ from the claimed plants, fruits and seeds only by their method of making, namely the selection step. However, the method of making the claimed interspecific tomato plants with altered starch accumulation would not confer a unique property to these plants which would distinguish them from the prior art interspecific tomato plants with altered starch accumulation. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 1-2, 7, 9, 17-19, 23, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewitt et al in light of with Rick, further in view of Dinar et al.

Hewitt et al in light of Rick teach an interspecific tomato line with high soluble solids in the mature fruit and high starch production in the immature fruit as discussed above, but do not teach a method of selecting tomato fruits with high starch accumulation for breeding purposes.

Dinar et al teach the desirability of selecting tomato lines with high soluble solids in the mature fruits, and also teach the correlation between high starch accumulation in immature 'LA 1563' fruits and high soluble solids content in mature 'LA 1563' fruits (see, e.g., page 415, first paragraph of column 1, first paragraph of 'Materials and Methods', and Abstract; page 416, Tables 1 and 2; page 418, column 1, third paragraph).

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It would have been obvious to one of ordinary skill in the art to utilize interspecific *Lycopersicon* crosses to produce tomato lines bearing fruits with altered starch and soluble solids content as taught by Hewitt et al taken with Rick, and to assay for the production of starch in immature fruit as a predictor of total soluble solids content in mature fruit; as suggested by the correlation of these traits taught by Dinar et al, the desirability of high soluble solids content as taught by Dinar et al, and the recognition by those of ordinary skill in the breeding art of the advantages of reducing the time needed to assay for desirable traits. Choice of assaying for starch content or for the activity of an unspecified enzyme involved in starch content would have been the optimization of process parameters.

Claims 3-6, 8 and 10 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of producing tomatoes with altered starch accumulation, said method comprising crossing *L. esculentum* with *L. hirsutum* and selecting for either increased starch synthesis or ADPGPPase activity in the young fruit, or for using molecular markers to select for the *L. hirsutum* allele encoding the large subunit of that enzyme.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

September 30, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

*David T. Fox*